**2004/008** 

## AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

# **Listing of Claims:**

## 1-2 (Canceled)

3(Previously Presented). A method as claimed in claim 5 wherein the kallikrein 5 is detected using antibodies specifically reactive with kallikrein 5 or a part thereof.

#### 4 (Canceled).

5(Previously Presented). A method for detecting or screening a subject for breast or ovarian cancer comprising

- (a) obtaining a biological sample from a subject;
- **(b)** detecting the amount of kallikrein 5 in said sample; and
- comparing said amount of kallikrein 5 detected to a predetermined (c) standard, where detection of a level of kallikrein 5 greater than that of a standard is indicative of breast or ovarian cancer.

6(Original). A method of claim 5 wherein the level of kallikrein 5 is 2X, 5X, 10X, 15X, or 20X the levels of the standard.

## 7-8 (Canceled).

9(Previously Presented). A method for monitoring the progression of breast or ovarian cancer in a subject, the method comprising: (a) detecting in a sample from the subject at a

first time point, kallikrein 5; (b) repeating step (a) at a subsequent point in time; and (c) comparing levels detected in steps (a) and (b), and thereby monitoring the progression of breast or ovarian cancer.

10(Previously Presented). A method of claim 5 for screening a subject for breast or ovarian cancer comprising

- (a) incubating a biological sample from the subject with a first antibody specific for kallikrein 5 which is directly or indirectly labeled with a detectable substance, and a second antibody specific for kallikrein 5 which is immobilized;
- (b) detecting the detectable substance thereby quantitating kallikrein 5 in the biological sample, and
- (c) comparing the quantitated kallikrein 5 with levels for a predetermined standard.

11(Previously Presented). A method of claim 5 wherein the biological sample is serum.

12(Previously Presented). A method of claim 5 which further comprises detecting one or more of human stratum corneum chymotryptic enzyme (HSCCE), haptoglobin alpha, osteopontin, kallikrein 2, kallikrein 3, kallikrein 4, kallikrein 6, kallikrein 7, kallikrein 8, kallikrein 9, kallikrein 10, kallikrein 11, kallikrein 13, kallikrein 14, kallikrein 15, CA125, CA15-3, CA19-9, OVX1, lysophosphatidic acid (LPA) or carcinoembryonic antigen (CEA).

13(Withdrawn). A method for assessing the potential efficacy of a test agent for inhibiting breast or ovarian cancer in a subject, the method comprising comparing: (a) levels of kallikrein 5 in a first sample obtained from a subject and exposed to the test agent; and (b) levels of kallikrein 5 in a second sample obtained from the subject, wherein the sample is not exposed to the test agent, wherein a significant difference in the levels of expression of kallikrein 5 in the first sample, relative to the second sample, is an

indication that the test agent is potentially efficacious for inhibiting breast or ovarian cancer in the subject.

14(Withdrawn). A method of claim 13 wherein the first and second sample comprises portions of a single sample obtained from the subject.

15(Withdrawn). A method of claim 13 wherein the first and second sample comprises portions of pooled samples obtained from the subject.

16-25 (Canceled).

26(Previously Presented). A kit for assessing whether a subject is afflicted with breast or ovarian cancer, the kit comprising reagents that specifically bind with kallikrein 5.

27(Canceled).

28(Previously Presented). A kit as claimed in claim 26 wherein the reagents are antibodies that specifically bind with protein or protein fragments corresponding to kallikrein 5.

29(Previously Presented). A method of claim 5 wherein the standard comprises normal levels of kallikrein 5 in samples of the same type obtained from control subjects not afflicted with breast or ovarian cancer.

30(Previously Presented). A method of claim 29 wherein the level of kallikrein 5 in the sample is 2X, 5X, 10X, 15X, or 20X the normal levels.

31(Previously Presented). A method of claim 9 wherein the biological sample is serum.

32(Previously Presented). A method of claim 10 wherein the biological sample is serum.

33(Previously Presented). A method of claim 13 where the significant difference is a decrease in the levels of expression of kallikrein 5.